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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/380,336	11/23/1999	JOHANNES WILLEM HOFSTRAAT	AEM2527PIUS	2490

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EXAMINER

GABEL, GAIENE

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/380,336	Applicant(s) HOFSTRAAT, JOHANNES WILLE	
	Examiner Gailene R. Gabel	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-10 is/are rejected.
- 7) ☒ Claim(s) 4 and 10 is/are objected to.
- 8) ☒ Claim(s) 1-14 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendment Entry

1. Applicant's amendment and arguments filed 3/15/04 is acknowledged and has been entered. Claims 3, 4, 6, 9, and 10 have been amended. Claims 1-14 are pending and are under examination.

Claim Objections

2. Claim 10 is objected to because of the following informalities: Independent claim 10 is an exact duplicate of claim 1. Appropriate correction is required.

Rejections Maintained

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-4, 6, 7, 10, and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step is a separation step to remove unbound components. It is thus, unclear how the detected luminescence measurement [used]

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can be differentially measured from unbound (labeled) reactant or immunoreactant.

Additionally, Applicant admits by way of disclosure, that the separation step is critical in the practice of the invention; however, it is not recited in the rejected claims.

Accordingly, claim 1 is vague and indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step is a separation step to remove unbound components. It is thus, unclear how the detected luminescence measurement [used] can be differentially measured from unbound (labeled) reactant or immunoreactant.

Additionally, Applicant admits by way of disclosure, that the separation step is critical in the practice of the invention; however, it is not recited in the rejected claims.

Accordingly, claim 1 is vague and indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-3 and 5-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wieder et al. (US 5,830,769) in view of Kardos et al. (US 6,159,686) for reason of record.

Response to Arguments

5. Applicant's arguments filed 3/15/04 have been fully considered but they are not persuasive.

The Rule 132 Declaration by Dr. Brenner explained the structural difference between the present invention and the teachings of Wieder et al. and Kardos et al.; however, the present invention as described by Dr. Brenner is not reflected in the recited claims.

A) Applicant argues that the combination of Wieder and Kardos does not render obvious the claimed invention because the language of claims 1 and 10 require that the preparation of the lanthanide ion-ligand complex comprises a sensitizing moiety. Applicant therefore contends that the sensitizing moiety, which is a component of the ligand, is required to be part of the lanthanide ion-ligand complex. Applicant argues that this is contrary to Wieder's teaching of the rhodamine or fluorescein moiety which is added to the solution as a separate component and brought to a certain distance from the lanthanide ion-ligand complex, wherein the sensitizing moiety (=ligand) is polyaminocarboxylic acid, pyridine, etc.

In response, claims 1 and 10 only recite that the ligand in the lanthanide ion-ligand complex of the instant invention *comprises* a sensitizing moiety. Both of claims 1

and 10 do not to exclude that the sensitizing moiety is added as a separate component into the complex. Accordingly, the claims 1 and 10 read on the teaching of Wieder et al.

Allowable Subject Matter

6. Claim 4 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims and if the base claims are rewritten or amended to overcome the rejections under 35 U.S.C. 112, second paragraph, set forth in this Office action. The prior art of record does not teach or fairly suggest that the ligand in the lanthanide ion-ligand complex consists of a compound having an element selected from the group consisting of oxygen, nitrogen, phosphorus, and sulfur moieties which complexes with Nd(III), Yb(III), and Er(III) ions and the sensitizing moiety is selected from the group consisting of fluorescein derivatives, rhodamine derivatives, etc. (recited in claim 4).

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday, Tuesday, and Thursday, 5:30 AM to 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-0169.

Gailene R. Gabel
Patent Examiner
Art Unit 1641
June 10, 2004

fg

Christopher L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800-1641